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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,309	11/29/2000	Alok Singh	79,212	8594

7590 05/24/2004

Associate Counsel (Patents), Code 1008.2  
Naval Research Laboratory  
Washington, DC 20375-5000

EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/725,309	<b>Applicant(s)</b> SINGH ET AL.	
	<b>Examiner</b> Richard G Hutson	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,4,7-15,21 and 23-26 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☒ Claim(s) 3,4,7,8,15,24 and 25 is/are allowed.  
 6) ☒ Claim(s) 9-14,21,23 and 26 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 3, 4, 7-15 and 21, 23-26 are still at issue and are present for examination.

Applicants' arguments filed on 3/11/2004 have been fully considered and are not deemed to be persuasive to overcome the rejections previously applied for the reasons stated.

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### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 9-12, 14, 21, 23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Xiao et al.(U.S. Patent No. 6,593,099 B2).

The rejection was stated in the previous office action and repeated below for applicants convenience. In response to this rejection applicants have filed a declaration under 1.131.

The declarations filed on 3/11/2004 under 37 CFR 1.131 has been considered but is ineffective to overcome the Xiao et al. reference for the following reasons:

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Applicants declaration(s) must be signed by "All of the inventors of the subject matter claimed" as per MPEP Section 715.04. Applicants declarations indicate that the signers of each declaration are "co-inventors of the claimed invention, thus the other co-inventors must sign the declaration.

Applicants declaration(s) have not stated that the "Acts relied upon were carried out in this country or a NAFTA or WTO Member Country" as required by MPEP Section 715.07 (c).

Correction of the above formal matters would result in the withdrawal of the rejections based on Xiao et al. (U.S. Patent No. 6,593,099 B2).

Claims 9-12, 14, 21, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Journal of the American Oil Chemist's Society, Vol 76, No. 10, pp 1113-1118, 1999).

Lee et al. teach a method comprising genetically engineering *E. coli* thioesterase I with a hexahistidyl peptide (His-tag) extension attached to the C-terminus and

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attaching the genetically engineered thioesterase to a metal salt of nitrilotriacetic acid  
(See Materials and Methods).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao et al.(U.S. Patent No. 6,593,099 B2) and Lu et al. (Journal of Biological Chemistry, Vol 271, No. 9, pages 5059-5065, March 1996).

The rejection was stated in the previous office action. In response to this rejection applicants have filed a declaration under 1.131.

As discussed above, the declarations filed on 3/11/2004 under 37 CFR 1.131 has been considered but is ineffective to overcome the Xiao et al. reference for the reasons stated above.

Correction of the above formal matters would result in the withdrawal of the rejections based on Xiao et al. (U.S. Patent No. 6,593,099 B2).

Claim 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Journal of the American Oil Chemist's Society, Vol 76, No. 10, pp 1113-1118, 1999)

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and Lu et al. (Journal of Biological Chemistry, Vol 271, No. 9, pages 5059-5065, March 1996).

As discussed above, Lee et al. teach a method comprising genetically engineering *E. coli* thioesterase I with a hexahistidyl peptide (His-tag) extension attached to the C-terminus and attaching the genetically engineered thioesterase to a metal salt of nitrilotriacetic acid (nickel-nitrilotriacetic acid).

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Lu et al. teaches similar methods, as those taught by , Lee et al., of protein purification of *E. coli* thioredoxins, with the following exceptions. Lu et al. rather than add a 6X His sequence to the amino or carboxyl terminus of the protein, mutate selective surface exposed residues to histidine and in addition to nickel-nitrilotriacetic acid (NTA) salts, Lu et al. use copper- and nickel-iminodiacetic acid (IDA) salts. Lu et al. teach that both the IDA and NTA salts resulted in identical protein affinity results (page 5061, top of column 2).

One of ordinary skill in the art at the time of filing would have been motivated to use either nickel-nitrilotriacetic acid (NTA) salts as used by Lee et al. and Lu et al. or nickel-iminodiacetic acid (IDA) salt as used by Lu et al. to isolate the thioesterase fusion produced by Lee et al. because Lu et al. teach that both the IDA and NTA salts resulted in identical protein affinity results. The reasonable expectation of success comes from the high degree of knowledge in the field as demonstrated by the results of Lee et al. and Lu et al., who successfully genetically engineered and isolated a number of different enzymes to contain a poly-histidine tail. Thus claim 13 is made obvious by Lee et al. and Lu et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
5/19/2004